

### **REMARKS**

Claims 1-18 were originally filed. In response to the restriction requirement mailed 28 April 2000, Applicants elected, with traverse, the claims of Group IX, claims 14-18. In the present amendment, Applicants have canceled claims 1-13, 17, and 18, and added new claims 19-35. Therefore, claims 14-16 and 19-35 are currently under examination. Attached hereto is a marked-up version of the changes made by the present amendment. The attached page is captioned "Version with markings to show changes made."

Justification for the amendments is as follows. The amendments were made to further clarify the claims. Support for the disorders identified in amended claim 14 and new claims 20 and 23 can be found in the specification, e.g., on page 9, lines 30-31. Support for the conditions identified in new claims 27, 30 and 33 can be found in the specification, e.g., on page 10, line 29, and page 18, lines 24-30. Support for the use of CTGF-specific antibodies to detect CTGF as described in new claims 19, 22, 26, 29, 32, and 35 can be found in the specification, e.g., on page 39, lines 13-14. No new matter is added by any of the above amendments.

Claims 1-13, 17, and 18 have been cancelled without prejudice to renewal. Applicants reserve the right to pursue the subject matter of the cancelled claims in future divisional applications.

## I. Rejection under 35 U.S.C. 102(b)

The Examiner maintained the rejection of claims 14 and 15 under 35 U.S.C 102(b) as being anticipated by Grotendorst and Bradham, WO 96/38172. Specifically, the Examiner stated "the `172 patent does teach the detection of kidney fibrosis by detecting CTGF. The mere fact that the `172 patent doesn't recognize that kidney fibrosis results in an overproduction of extracellular matrix is not relevant due to the fact that prior to Applicant's invention it was well known in the art that kidney fibrosis results in an overproduction of extracellular matrix."

Applicants do not agree. As stated in Applicants response mailed 2 July 2002, WO 96/38172 relates to methods of diagnosing pathologies characterized by a *cell proliferative disorder*, and identifies kidney fibrosis as a disease "in which there is an overgrowth of connective tissue cells". (WO 96/38172, page 7, lines 15 to 17.). Thus, WO 96/38172 does not necessarily address *all* kidney fibrotic disorders, but a subset of such disorders that are associated with "an overgrowth of connective tissue cells".

CKET NUMBER FP0806

However, to expedite prosecution, Applicants have amended the claims. As amended, claim 14 recites "a method of diagnosing a renal disorder selected from the group consisting of diabetic nephropathy, glomerulosclerosis, and glomerulonephritis." As WO 96/38172 does not disclose measuring CTGF as a diagnostic for these disorders, the reference does not anticipate claim 14 or dependent claim 15.

Therefore, Applicants respectfully request withdrawal of the rejection of claims 14 and 15 under 35 U.S.C. 102(b) as being anticipated by WO 96/38172.

# II. Rejections under 35 U.S.C. 103

The Examiner rejected claims 17 and 18 under 35 U.S.C. 103 as being unpatentable over WO 96/38172 in view of U.S. Patent 4,281,061.

Applicants have canceled claims 17 and 18. Therefore, the rejection of these claims under 35 U.S.C. 103 is moot.

#### CONCLUSION

In view of the foregoing, Applicant submits that the claims are fully in condition for allowance and request early notification to that effect. If the Examiner has any questions regarding the present communication or the above-referenced application, please call Applicant's Agent at 650-866-7265.

Applicants believe that no fee is due with this communication. If, however, the Commissioner determines that a fee is due, the Commissioner is hereby authorized to charge any necessary fees to Deposit Account No. 50-0811. This form is enclosed in duplicate.

Respectfully submitted,

DATE: \_ 30 April 2003

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# VERSION WITH MARKINGS TO SHOW CHANGES MADE

### IN THE CLAIMS

Claims 1-13, 17, and 18 have been canceled.

Claims 14 and 15 have been amended as follows:

- 14. (Again Amended) A method for diagnosing glomerulosclerosis [a renal disorder characterized by overproduction of extracellular matrix, or identifying a predisposition or susceptibility to a renal disorder characterized by overproduction of extracellular matrix,] in a subject, the method comprising:
  - (a) obtaining a sample from the subject;
  - (b) detecting the level of CTGF protein in the sample; and
  - (c) comparing the level of CTGF protein in the sample to a standard level of CTGF protein, wherein increased levels of CTGF protein are indicative of the presence of glomerulosclerosis [a renal disorder].
- 15. (Once Amended) The method of claim 14, wherein the <u>glomerulosclerosis</u> [renal disorder] is <u>associated with diabetes</u>.